1. Introduction

The Air Toxics "Hot Spots" Information and Assessment Act (AB 2588, Connelly, stat. 1987; Health and Safety Code Section 44300 et seq.) is designed to provide information on the extent of airborne emissions from stationary sources and the potential public health impacts of those emissions. Facilities provide emissions inventories of chemicals specifically listed under the "Hot Spots" Act to the local Air Pollution Control and Air Quality Management Districts and ultimately to the state Air Resources Board. Following prioritization of facilities by the Districts, facilities may be required to conduct a health risk assessment. Health risk assessment involves a comprehensive analysis of the dispersion of emitted chemicals in the air and the extent of human exposure via all relevant pathways (exposure assessment), the toxicology of those chemicals (dose-response assessment), and the estimation of cancer risk and noncancer health impacts to the exposed community (risk characterization). Most "Hot Spots" risk assessments are conducted by contractors for the facility; some are conducted in-house and some by the local air districts.

The Air Toxics "Hot Spots" Act was amended to require that the Office of Environmental Health Hazard Assessment (OEHHA) develop risk assessment guidelines for the Air Toxics "Hot Spots" program (SB 1731, Calderon, stat. 1992; Health and Safety Code Section 44360(b)(2)). The amendment specifically requires OEHHA to develop a "likelihood of risks" approach to health risk assessment; OEHHA has, therefore, developed a stochastic, or probabilistic, approach to exposure assessment to fulfill this requirement. The stochastic approach described in this document provides guidance to the facility operators who want to conduct a stochastic risk assessment, and facilitates use of supplemental information to be considered in the health risk assessment.

Information on both dose-response relationship and exposure is required in order to quantify estimates of health risks. OEHHA has developed a series of documents describing the information supporting the dose-response assessment for "Hot Spots" chemicals and the exposure assessment methodologies. Part I, "Technical Support Document for the Determination of Acute Toxicity Exposure Levels for Airborne Toxicants" (March 1999) describes acute Reference Exposure Levels for approximately 50 chemicals and the methods used to determine those levels. Part II, "Technical Support Document for Determining Cancer Potency Factors" (April 1999), describes the methods and results of determining cancer potency factors for approximately 120 carcinogens. Part III, "Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels for Airborne Toxicants" (February, 2000), describes the methods of determining chronic Reference Exposure Levels (REL) and 38 chronic RELs for use in estimating noncancer health impacts from chronic exposure. Additional chronic RELs are currently undergoing peer review. The purpose of this document Part IV, "Technical Support Document for Exposure Assessment and Stochastic Analysis" is to describe the exposure algorithms, and point estimates and distributions of key exposure variates that can be used for the exposure analysis component of Air Toxics "Hot Spots" risk assessments. The document includes a description of the point estimate and stochastic multipathway exposure assessment approaches and a brief summary of the information supporting the selection of default assumptions.

OEHHA developed this document in consultation with the Air Resources Board (ARB) and the California Air Pollution Control Officers Association (CAPCOA). In addition, OEHHA formed an External Advisory Group (EAG) to help evaluate the information used in the stochastic exposure analysis. This group was composed of representatives from industry, environmental organizations, universities, the CAPCOA Toxics Committee, ARB, the Department of Pesticide Regulation, the Department of Toxics Substances Control, and the U.S. Environmental Protection Agency (EPA). The purpose of the EAG was to get early input from stakeholders into the preparation of the stochastic methodology. Meetings of the EAG were held every 4 to 6 weeks to discuss available data on key exposure variates and the characterization of the distributions of key exposure variates.

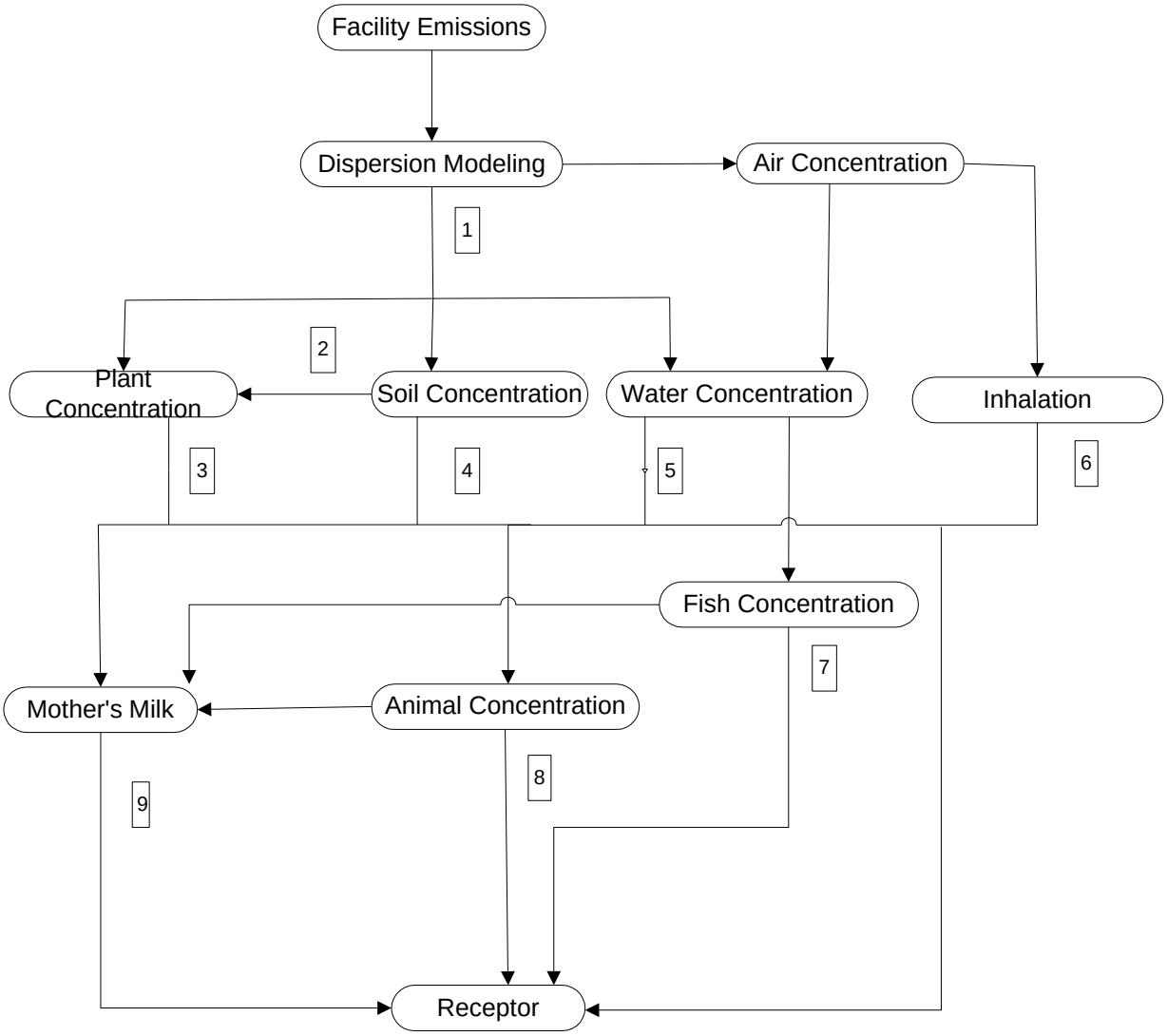
Finally, a companion document is being developed, "Air Toxics 'Hot Spots' Risk Assessment Guidance Manual", which contains the essential information to conduct a health risk assessment based on the four technical support documents described above.

1.1 Multipathway Nature of Exposure Assessment

Exposure assessment of airborne emissions includes not only an analysis of exposure via the inhalation pathway, but also noninhalation pathways of indirect exposure to airborne toxicants. There are data in the literature demonstrating that for some compounds, significant exposure occurs following deposition of airborne material onto surface water, soils, edible plants (both food, pasture and animal feed), and through ingestion of breast milk. Examining both direct inhalation and indirect noninhalation exposure pathways reveals the full extent of exposure to airborne emissions (see Figure 1.1). However, only certain chemicals are evaluated via the multipathway approach in the Air Toxics "Hot Spots" risk assessments. In general, there is a higher potential for indirect exposure to chemicals which tend to bioconcentrate or bioaccumulate (e.g., lipophilic semi-volatile organics), or otherwise accumulate in the environment (e.g., metals). Semi-volatile organic and metal toxicants can be directly deposited onto surface waters, soil, leaves, fruits and vegetables, grazing forage, and so forth. This is particularly important when these chemicals are associated with particulate matter. Cows, chickens, and other food animals can become contaminated through inhalation, and ingestion of contaminated surface water, pasture, feed and soil. Fish can become contaminated via bioconcentration from water and bioaccumulation from their food (the latter is not considered under these guidelines). Produce can become contaminated via root uptake from soils and direct deposition. Thus, humans can be exposed through ingestion of contaminated meat, fish, produce, water and soil, as well as from breathing contaminated air, and via dermal exposure. In addition, nursing infants can be exposed via breast milk.

Inhalation exposure is assessed for all "Hot Spots"-listed chemicals which have either Cancer Potency Factors and/or Reference Exposure Levels (see Technical Support Documents, Parts I, II, and III for information on these values (OEHHA, 1999a, 1999b, 2000)). The noninhalation exposures are assessed only for semivolatile organics and metals listed in Appendix E, Table E.2. Appendix E contains a description of the process used to decide which

Figure 1.1 Exposure Routes



1. Deposition
2. Root Uptake by plants.
3. Human Consumption of Leafy, Protected, Exposed and Root Produce. Animal consumption of pasture and feed.
4. Soil Ingestion by humans and animals.
5. Water consumption from surface water sources
6. Inhalation by humans and animals
7. Fish consumption
8. Consumption of beef, chicken and pork.
9. Mother's milk consumption.

chemicals should be evaluated by multipathway exposure assessment. Only the exposure pathways which exist at a particular site need to be assessed. For example, if a fishable body of water is impacted by facility emissions, then exposure through consumption of angler-caught fish is assessed. Otherwise, that pathway may be omitted from the risk assessment. Likewise if no backyard or commercial produce or animals are raised in the impacted area, then the risk assessment need not consider dose through the ingestion of animal food products or produce. The "Hot Spots" program does not currently assess runnoff into surface drinking water sources because of the complex site-specific information required. The water consumption of surface waters pathway is rarely invoked in the "Hot Spots" program. All risk assessments of facilities emitting chemicals listed in Table E.2 need to include an evaluation of exposure from breast milk consumption, soil ingestion, and dermal absorption from soil, since these exposure pathways are likely to exist at all sites. Table E.3 lists the chemicals that should be evaluated by the breast milk exposure pathway. The determination of the appropriate exposure pathways for consideration in the risk assessment should be made in conjunction with the local Air Pollution Control or Air Quality Management District. Justification for excluding an exposure pathway should be clearly presented.

1.2 The Point Estimate Approach

Traditionally, site-specific risk assessments have been conducted using a point estimate (sometimes referred to as a deterministic) approach in the exposure and risk model. In the point estimate approach, a single value is assigned to each variate in the model (e.g., breathing rate is assumed to be 20 m^3/day, body weight to be 70 kg). The point estimates chosen sometimes represent upper-end values for the variate and sometimes reflect a mean or central tendency estimate. The outcomes of a point estimate model are single estimates of either cancer risk or of the hazard index for noncancer effects. The point estimates of risk are generally near the high-end of the range of estimated risks and are therefore protective of public health.

OEHHA is providing guidance in this document on the point estimate approach including both algorithms and default values where appropriate. OEHHA started with the current methods used in the Air Toxics "Hot Spots" program as described in the CAPCOA Air Toxics "Hot Spots" Program Revised 1992 Risk Assessment Guidelines, October 1993 (CAPCOA, 1993). These algorithms are consistent with the U.S. EPA Risk Assessment Guidance for Superfund and are widely used. The algorithms and point estimate values were reevaluated for their utility, and whether they represent the best scientific approach. The evaluation showed that the existing algorithms were appropriate for the point estimate approach. A number of the point estimate values for exposure factors or variates were updated based on literature reviews. Some values (e.g., soil ingestion rates, dermal exposure factors) are adopted from U.S. EPA documents (U.S. EPA 1991, 1997). The mean of exposure variate values from several equally regarded studies was used when appropriate. When OEHHA developed or adopted a distribution for an exposure variate, the information from the distributions was used to determine central tendency and high end point estimates. OEHHA has used the arithmetic mean to reflect central tendency and the 95% upper confidence limit to represent a high-end estimate in this document.

U.S. EPA (1995) promotes the use of risk descriptors for "(1) individual risk that include central tendency and high-end portions of the risk distribution, (2) population risk and (3) important subgroups of the population, such as highly exposed or highly susceptible groups" (U.S. EPA, 1995, attachment p. 12). The U.S. EPA (1992) Guidelines for Exposure Assessment state "conceptually, high-end risk means risks above the 90th percentile of the population distribution but not higher than the individual in the population who has the highest risk." Similarly, high end of exposure is presented as ranging from the 90th to the 99.9th percentile (U.S. EPA, 1992, p. 22923). U.S. EPA (1995) risk characterization guidance states that it will be difficult to estimate exposures or doses and associated risk at the high end with much confidence if very little data are available on the range of a variate. U.S. EPA further state "One method that has been used in such cases is to start with a bounding estimate and "back off" the limits used until the combination of parameter values is, in the judgment of the assessor, within the distribution of expected exposures, and still lies within the upper 10% of persons exposed. Obviously, this method results in a large uncertainty and requires explanation." (U.S. EPA, 1995, p. 15). OEHHA has not established any bounding estimates in this document or used this method to create a high-end estimate. "Central tendency" is meant to reflect typical or average estimates of exposure. U.S. EPA (1995) bases central tendency on either the arithmetic mean or median exposure estimate.

Frequently, there are little data for identifying point estimate values for exposure variates. This makes evaluation of the information and choice of a scientifically defensible value difficult. When the data are limited, a mean value derived from scientifically valid studies is the most defensible, as it is the best estimate of the central tendency and is less uncertain than an upper or lower end estimate. OEHHA has chosen a central tendency estimate (mean or approximation of the mean) when little data are available to evaluate a specific variate. If there are enough data to generate a mean and high-end estimate, then OEHHA has provided both the mean and a high-end estimate for those variates.

A tiered approach to risk assessment including point estimate methods, which allows for both consistency and flexibility, is described in Section 1.4. OEHHA's proposed algorithms and default point estimates for each major exposure pathway are described in Chapters 3 through 11. Information supporting the choice is briefly summarized in each section.

The point estimate approach has the advantages of simplicity and consistency, and in the Air Toxics "Hot Spots" program consistent application across the state is critical to comparing risks across facilities for the notification and risk reduction provisions of the statute. Risk communication is relatively straightforward with a point estimate approach. However, quantitative risk assessment is associated with much uncertainty. A single point estimate approach provides only limited information on the variability in the dose or risk estimates. Information about the potential range of risks in the population is presented as average or high-end point estimates of risk.

1.3 The Stochastic Approach ("Likelihood of Risks" Approach)

Quantitative risk estimates are uncertain. In common use, the term "uncertainty" in a risk estimate can be viewed as composed of variability as well as true uncertainty in exposure and dose-response. As noted in U.S. EPA (1995), true uncertainty represents lack of knowledge about a variate or factor that impacts risk which may be reduced by further study. There are uncertainties associated with measurement, with models of environmental fate (e.g., air dispersion models), and with dose-response models. Uncertainty may stem from data gaps that are filled by the use of assumptions.

Variability can be measured empirically in data describing an exposure variate. Variability arises from true heterogeneity in characteristics of a population such as differences in rate of intake of various media (air, water, food, soil). The stochastic analysis approach attempts to quantify some of the "uncertainty" in the risk estimates by using measured variability in data describing key exposure variates to characterize the distribution of that variate. Under the stochastic approach, a distribution of values is used as input for one or more variates in the model. Using statistical methods, such as Monte Carlo simulation, to propagate the variance of exposure variates through the model, the risk estimates are expressed as a range rather than as a single point estimate.

Note that the stochastic approach employed in the Air Toxics "Hot Spots" program does not address either exposure model uncertainty or true uncertainty about a variate that is not reflected in the measured variance of the exposure variate. This lack of information (true uncertainty) may occur because a variable is not currently measurable with available scientific methods, the accuracy in measuring the variable is unknown, or there is otherwise a lack of knowledge about the variable. Although stochastic methods like the one described in this document are frequently referred to in the risk assessment literature as "uncertainty" analyses, in reality, they may deal only with the measured variability in those variates treated stochastically, and not with true uncertainty.

The primary benefits of stochastic analysis are the quantitative or semi-quantitative treatment of variability in risk estimates and the increase in information on which to base decisions. In contrast, a point estimate approach generally treats variability and uncertainty in the risk estimate qualitatively, if at all. The disadvantages of the stochastic approach include the resource-intensive nature of such an analysis, difficulty in treating true uncertainty, that is, lack of knowledge about factors which impact the risk estimate, and difficulty in communicating the results to risk managers and the public. In order to use a stochastic approach fully, much work needs to go into the characterization of probability distributions for key exposure variates, and one may still be unable to treat the major sources of uncertainty due to a lack of data. Since stochastic analysis is resource-intensive, this approach is more appropriate when addressing important problems that merit the necessary effort.

Neither the stochastic approach nor the point estimate approach to exposure assessment presented in this document deals with uncertainty or variability in the dose-response assessment. While human variability in response to toxicants is an increasingly active area of

research, more data are needed to better account for human interindividual variability in risk assessments.

In deciding which variates were important and amenable to stochastic analysis, OEHHA considered several criteria. First, the importance of a given pathway in the multipathway analysis of risk was taken into consideration. All chemicals in a "Hot Spots" risk assessment are evaluated via the inhalation pathway. Therefore, OEHHA chose to evaluate data on minute ventilation and activity patterns to develop distributions for daily breathing rates for adults and children. Second, for each indirect noninhalation pathway, OEHHA evaluated data describing the key intake variate in order to characterize distributions for those important inputs. For example, the distribution of breast milk consumption in the first year of life was characterized using raw data on consumption from published studies. Two important considerations in developing the distributions in this document were the importance of the exposure pathway relative to inhalation exposure and the quality of data available to characterize the value of key variates. We chose not to develop distributions applicable to the soil ingestion pathway because data available to characterize soil ingestion rates are problematic. We also chose not to develop distributions for the variates involved in the dermal pathway because this pathway is less important overall and data available for some variables are extremely limited.

The exposure distributions developed were designed to cover from age 0-9 years and age 0-70 years. The exception to this is the breast milk consumption distribution that is only for the first year of life. Nine and 70-year distribution are simulated where necessary, using Monte Carlo methods. These distributions can be used for evaluating the 9- and 70-year exposure durations which are recommended in this document. In the interest of simplicity, we are recommending that 0-70 year distributions be used for evaluating the 30-year exposure duration. The 0-9 year distributions are based on the first 9 years of life in which exposure on a per kg body weight basis and thus dose is greater than for adults. Thus the 9-year distributions are appropriate for children but will overstate the risk for 9 years of an adult exposure.

We have taken the approach that enough data must be available to adequately characterize a distribution. While some papers in the risk assessment literature make speculative assumptions about the shape of an input distribution in the absence of data, this cannot be readily justified in most cases. Additional assumptions regarding a distribution in the absence of data may increase uncertainty and may not improve the knowledge about the range of risks in a population.

In analyzing distributions, OEHHA gathered information on existing point estimates and distributions for key exposure variates in use by Cal/EPA or U.S. EPA, and suggested in the literature or in available documents (e.g., the American Industrial Health Council's Exposure Factors Sourcebook). The underlying bases for the distributions were evaluated for applicability to the Air Toxics "Hot Spots" program. In some instances available distributions were found to be useful in their current form. Some distributions were modified by adding more recent information. In other instances, OEHHA chose to characterize a distribution from available raw data. In general, the statistical package SAS® was used in the Proc Univariate mode to analyze

distributions from raw data. More detail is provided in each individual section on the characterization of the distributions.

There are undoubtedly exposure variates for which distributions could be characterized based on available data. However, due to resource and time constraints, OEHHA evaluated those exposure intake variables that are likely to have greater impacts on quantitative estimates of risk and for which there are useful data to characterize a distribution (see Chapters 3 through 11). We hope to develop additional distributions in the future.

1.4 Tiered Approach to Risk Assessment

Most facilities in the Air Toxics "Hot Spots" program may not require a complicated stochastic analysis for sufficient characterization of risks from emissions. In order to allow the level of effort in a risk assessment to be commensurate with the importance of the risk management decision, a tiered approach to risk assessment is recommended. The tiers are meant to be applied sequentially to retain consistency across the state in implementing the Air Toxics "Hot Spots" program while allowing flexibility.

The benefits of a tiered approach to site-specific risk assessment include lower costs to facilities conducting risk assessments, consistency across the state, comparability across facilities, and flexibility in the approach to assessing risks. A simple health-protective point estimate risk assessment will indicate whether a more complex approach is warranted, and will help prioritize limited resources. The tiered risk assessment approach facilitates use of site-specific supplemental information in the risk assessment to better characterize the risks. Finally, more information is available to risk managers and the public when a tiered approach is fully utilized.

1.4.1 Tier 1

Tier 1 is the first step in conducting a comprehensive risk assessment with a point estimate approach, using algorithms and point estimates of input values presented in the following chapters. Each facility conducts a Tier 1 risk assessment to promote consistency across the state for all facility risk assessments and allow comparisons across facilities.

Condensed guidance, including tables of the point estimate values recommended by OEHHA in Part IV, is given in the companion document "Office of Environmental Health Hazard Assessment Air Toxics "Hot Spots" Risk Assessment Guidelines" (to be released following completion of Parts I-IV). Site-specific values such as the volume of water in an impacted lake have to be provided by the risk assessor.

Mean and high-end point estimates for key exposure variates were estimated by OEHHA from available data. To be health-protective, high-end estimates for the key intake exposure variates are used for the dominant pathways in Tier 1.

If a risk assessment involves multipathway exposures, then the risk assessor needs to evaluate which pathways are dominant by conducting an initial assessment using the high-end

point estimates for those key intake variates, which have been evaluated by OEHHA. Dominant pathways are defined for these purposes as the two pathways that contribute the most to the total cancer risk estimate when using high-end estimates of key intake variates. High-end estimates for key intake variates for the two dominant pathways and mean values for key variates in the exposure pathways that are not dominant are then used to estimate risks. This will lessen the problem of compounding high-end exposure estimates while still retaining a health-protective approach for the more important exposure pathway(s). It is unlikely that any one person would be on the high-end for all the intake variates. It is our experience that inhalation is generally a dominant pathway posing the most risk in the Air Toxics "Hot Spots" program; occasionally risks from other pathways may also be dominant for lipophilic compounds or metals. Therefore, for many facilities emitting volatile chemicals, the inhalation pathway will be the only pathway whose risks are assessed using a high-end intake estimate. For the Air Toxics "Hot Spots" program, the point of maximum impact for cancer risks is the location with the highest risks using this method.

In some instances, a facility's emissions may not pose a cancer risk, but instead the driver is a noncarcinogen. OEHHA is recommending the hazard index (HI) approach to assess the potential for noncancer health impacts. The hazard index is calculated by dividing the concentration in air by the Reference Exposure Level for the substance in question and summing the ratios for all chemicals impacting the same target organ. The HI approach calculations and the estimate of the Reference Exposure Level do not necessarily directly involve inhalation rate. Therefore, the determination of mean and high-end estimate is not as easily applied.

There may be instances where a noninhalation pathway of exposure contributes substantially to a noncancer chronic hazard index. In these cases, the high-end estimate of dose is appropriate to use for the two dominant pathways' noninhalation hazard indices. The point of maximum impact for noncancer chronic health effects is the modeled point having the highest non cancer chronic hazard index (adding noninhalation and inhalation hazard indices when appropriate for systemic effects). There are no noninhalation pathways to consider in calculation of acute hazard indices.

The relatively health-protective assumptions incorporated into the Tier 1 risk assessment (e.g., high-end values for key variates in the driving pathways) make it unlikely that the risks are underestimated for the general population. If the results indicate that a facility's estimated cancer risk and noncancer hazard are below the level of regulatory concern, further analysis may not be warranted. If the results are above a regulatory level of concern, the risk assessor may want to proceed with further analysis as described in Tier 2 or a more resource-intensive stochastic modeling effort described in Tiers 3 and 4 to provide the risk manager with more information on which to base decisions. While further evaluation may provide more information to the risk manager, the Tier 1 evaluation is useful in comparing risks among a large number of facilities.

1.4.2 Tier 2

The risk assessor may want to analyze the risks using point estimates more appropriate for the site being evaluated. This second tier approach would replace some of the defaults recommended in this document with values more appropriate to the site. A Tier 2 risk assessment would use the point estimate approach with justifiable point estimates for important site-specific variates. Use of this supplemental site-specific information may help to better characterize the risks.

Certain exposure variates such as breast milk consumption or inhalation rate would not be expected to vary much from site to site. Other variates for which OEHHA has provided point estimates may vary significantly from site-to-site. If the facility has data indicating that an OEHHA point estimate value is not appropriate in their circumstance, they may provide an alternative point estimate value. For example, if there are data indicating that consumption of fish from an impacted fishable body of water is lower than the OEHHA-recommended fish consumption rate, then the facility can use that data to generate a point estimate for fisher-caught fish consumption from that body of water.

If site-specific values are substituted this should be justified. All data and procedures used to derive them should be clearly documented, and reasonable justification should be provided for using the alternative value. The Districts and OEHHA should be able to reproduce the point estimate from the data presented in the risk assessment.

In a Tier 2 approach, the risk assessor may want to present multiple alternative point estimate scenarios with several different assumptions encompassing reasonable “average” and “high-end” exposures for important pathways. This may be an issue in the case where data on a key exposure variate for that particular site are lacking. For example, in a case where soil ingestion is a dominant pathway, if a key variate in the model is the number of days children spend outdoors in contact with soil, it may be most appropriate to run the model more than once using several different assumptions about the exposure frequency. Such scenario development is easily communicated to the risk manager and the public, and serves as a semi-quantitative analysis of the exposure variability using a point estimate approach to risk assessment. In any risk assessment where alternative point estimates representing different exposure scenarios are presented, all information used to develop the point estimates need to be presented clearly in the risk assessment, and the risk assessment need to include a justification for the exposure scenarios developed.

If the risk is below a level of regulatory concern, further analysis may not be warranted. If the risk estimate is still above a level of concern, then the risk assessor may want to proceed with a more complex stochastic analysis as described in Tier 3 to get a fuller characterization of the uncertainty in the risk estimate.

1.4.3 Tier 3

The third tier risk assessment involves stochastic analysis of exposure using algorithms and distributions for the key exposure variates specified in this document. Point estimates

specified in this document for those exposure variates without distributions should be used. Since a stochastic approach to risk assessment provides more information about the range and probability of risk estimates, Tier 3 can serve as a useful supplement to the Tier 1 and 2 approach. In the third tier, variance propagation methods (e.g., Monte Carlo analysis) are used to derive a range of risk estimates reflecting the known variability in the inputs as described in the distributions characterized in this document. Recommended distributions for use in a stochastic analysis and the scientific bases for these distributions are provided in Chapters 3 through 11 of this document.

OEHHA is recommending that a stochastic analysis be performed for cancer risk assessment only. OEHHA is considering various issues that still need to be resolved in order to develop a useful noncancer stochastic risk assessment approach. This issue may be addressed in future updates of the document. OEHHA is recommending a point estimate approach only for assessing the impact of AB-2588 facilities on workers employed at nearby work sites. We have not developed a breathing rate distribution that would be appropriate for a stochastic offsite worker risk assessment.

Commercial software is available that can be used to conduct a stochastic analysis. OEHHA and the Air Resources Board are working towards a software product that will be available to the public and will be able to perform the point estimate and stochastic risk assessments.

1.4.4 Tier 4

A fourth tier risk assessment could also be conducted if site-specific conditions suggest that alternative or additional distributions (and point estimates) for variates may be more appropriate than those provided by OEHHA. In a Tier 4 risk assessment, the risk assessor could characterize the distribution of variates that are important to the overall calculation of risk for which OEHHA provides only a point estimate. Or, the risk assessor may wish to use distributions other than those supplied by OEHHA for important variates that impact the risk. The scientific basis and documentation for alternative and additional distributions should be presented clearly in the risk assessment. Clear, reasonable justification would need to be provided in the risk assessment for using alternative distributions or point estimates. Such distributions would be based on data from the literature or site-specific data gathered by the facility.

The quality of data would need to be sufficient to reasonably justify the selection of the parametric model (e.g., normal, lognormal, etc.) used to characterize the empirical distribution. It is not necessary, however, that the data fit a given parametric model as defined by conservative statistical criteria such as the Kolmogrov-Smirnoff test. If a distribution is nonparametric, it may be used as a custom distribution in a variance propagation model such as a Monte Carlo simulation.

In each case where alternate distributions or point estimates are used, it is important that the results be compared with the results obtained using any point estimates and/or distributions

recommended in this document by OEHHA (e.g., the Tier 1 and 3 risk assessments). This is necessary to identify the contribution of the new information to the risk assessment. The District and OEHHA staff and any interested parties should be able to easily verify the assumptions, and duplicate the results.

1.5 Exposure Assessment Pathways

Chapters 3 through 11 are organized by exposure pathway, and present the algorithms used for both the point estimate and stochastic approach to exposure assessment. The scientific basis for each recommended point estimate and distribution for key variates is presented. In the instances where the variate is site-specific (e.g., volume of a body of water), default point estimates or distributions are not provided. In general, key studies used in evaluating a point estimate value or distribution are briefly discussed along with procedures used to characterize the distribution.

1.6 Children's Exposures

In the 1996 Public Review Draft of this document (OEHHA, 1996), Chapter 5 Breast Milk Consumption Rate, the issue of weighting early in life exposures proportionally greater than later in life exposure is discussed. There is evidence for some chemicals that an early-in-life exposure to the same dose is more potent in causing cancer than later in life exposure (Drew et al., 1983, Peto et al., 1992). Although exposure to toxicants via the breast milk pathway is a very early in life exposure, early-in-life exposure also occurs via other pathways, for example, soil ingestion and food ingestion. We are mandated under SB-25 to evaluate if current OEHHA cancer potency factors, unit risk factors, and Reference Exposure Values are protective of children's health. As part of the SB-25 mandate, OEHHA will be evaluating the important issue of weighting early-in-life exposure and its significance in protecting public health. In addition, we are striving towards more complete evaluation of exposures to infants, young children, and adolescents. This requires more and better data than we have utilized as the basis for the distributions presented in this document for the 0 to 9 year exposure scenarios. This document will be updated as new data become available.

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